11.018.001

Dear
Astoria Historical Society or
whomsoever.

Here is a process control manual
of 30 years ago for the Castle & Cooke
Alaska operations. They were run out
of Astoria under John Supple including
the Seattle operations. Seattle became the
point of contact for day to day operations
but the chiefs remained in Astoria.

Some quality functions, esp Salmon (canned)
quality followed me to San Diego. The
function remained in Seattle esp after
Elaine Eglvedt retired.

I left Bumble Bee San Diego shortly
before it was sold to Connetion, part of
a large food purveyor and mfr.

A draft of the Tuna Q.C. manual was
left in S.D. I assume it was tossed
as my manager thought it "worthless" -
My opinion of my manager.

There should be several of these around
someplace, probably in Seattle

It's well written. Don't lend it out as
you won't get another.

Enjoy!

John Sattler 3/10/2011
Nashua, NH.

It's hard to give up something that ran 10 yrs of your life

CASTLE & COOKE, INC.

OFFICE CORRESPONDENCE

DATE: September 18, 1980

TO: Distribution

FROM: John Gaffke

SUBJECT: FDA INSPECTORS' "DOMESTIC ACIDIFIED AND LOW ACID CANNED FOOD INSPECTION REPORT"

Enclosed is the form and, thus, the format the FDA inspector uses when going through your plant. Review the information this form requests and fill out a copy in detail so you know how to answer the inspectors questions. Compare your answers with the directions issued by R. Mori in his April 23, 1980 memo on what to do when an inspector visits your plant.

Some of the details of your own operation you will discover in filling out this form may surprise you. Please show a copy of the blank form and the filled in form to the plant manager and your general manager.

Please submit a copy of your completed form with any questions to me.

JG:sd

Distribution: J. Farrell
K. White
R. Garcia

FYI: R. Mori
H. Eaton
H. Bisom
F. Jermann
K. Wong

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DOMESTIC ACIDIFIED AND LOW-ACID CANNED FOODS INSPECTION REPORT	CF NO. INSPECTION DATE(S)

LEGAL NAME OF FIRM	FCE NO.
ADDRESS *(Street, City, State, ZIP Code)*	
NAME OF INVESTIGATOR(S)	

SUMMARY OF FINDINGS

SUMMARIZE SIGNIFICANT FINDINGS

HISTORY OF BUSINESS

LEGAL STATUS ☐ CORPORATION ☐ PARTNERSHIP ☐ OTHER _____	IF INCORPORATED *(Give State)*	DATE INCORPORATED

NAME AND TITLE OF OFFICIALS

RELATED FIRMS

TRADE NAMES/BRANDS

SUMMARY OF PRODUCTS PRODUCED AND USUAL PRODUCTION SEASON(S)

FIRM NAME	CF NO.	INSPECTION DATE(S)

REGISTRATION AND PROCESS FILING

IS THE PLANT REGISTERED PER 21 CFR 108.25(c) OR 108.35(a)? ☐ YES ☐ NO

ARE PROCESSES FILED FOR ALL LACF AND ACIDIFIED PRODUCTS, INCLUDING LOW PRODUCTION ITEMS?
☐ YES ☐ NO IF NO, COMPLETE TABLE FOR PRODUCTS WITH NO PROCESS FILED.

(If additional space is required, use separate sheets)

NOTE: For flexible pouches, report container dimensions as follows: length *(longest dimension)* first, width *(second longest dimension)* second, and thickness *(smallest dimension)* last. Use the same industry convention regarding measurement in inches and sixteenths of an inch as is used for metal containers.

PRODUCT	NET WEIGHT	PACK STYLE	PACKING MEDIUM	CONTAINER DIMENSIONS	DATES PACKED	TYPE OF THERMAL PROCESSING SYSTEM

WERE SCHEDULED PROCESSES ESTABLISHED PER 113.83 OR 114.83? ☐ YES ☐ NO IF NO, EXPLAIN.

IF LACF PROCESSES HAVE BEEN CHANGED, NOTE EXTENT AND BASIS FOR CHANGE AND EFFECTIVE DATE. SEE 108.35 (a)(2)(ii)

HAVE REVISED LACF PROCESSES WHICH REFLECT THE ABOVE CHANGES BEEN FILED WITH FDA? ☐ YES ☐ NO

HAVE THERE BEEN MAJOR EQUIPMENT OR OPERATIONAL CHANGES SINCE THE ORIGINAL PROCESSES WERE ESTABLISHED?
☐ YES ☐ NO IF YES, DESCRIBE BELOW

DESCRIBE PROCEDURES OR WRITTEN PLANS FOR HANDLING PROCESS DEVIATIONS

FIRM NAME	CF NO.	INSPECTION DATE(S)

SCHEDULED PROCESSES AND CRITICAL FACTORS FOR PRODUCTS TO BE COVERED DURING THIS INSPECTION

PRODUCT NAME, STYLE AND PACKING MEDIUM	CAN SIZE	TYPE RETORT	VENT TIME/TEMP.	I. T.	PROCESS TIME/TEMP.	CRITICAL FACTORS AND TARGET VALUES

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

MOST RESPONSIBLE OFFICIAL'S NAME AND TITLE

MAILING ADDRESS *(Street, city, state, ZIP code)*

RESPONSIBILITY	NAME/TITLE
SCHEDULED PROCESS AND MODIFICATIONS	
APPROVAL OF PROCESS RECORDS	
EVALUATION OF PROCESS DEVIATIONS	
RELEASE OF LOTS	
PURCHASE OF EQUIPMENT	
HIRING/FIRING	
QUALITY CONTROL	
FORMULATION AND STANDARDS COMPLIANCE	
OTHER *(Specify)*	

PERSONS INTERVIEWED	NAME/TITLE
SHOWN CREDENTIALS	
RECEIVED FDA FORMS	
ACCOMPANIED INVESTIGATOR	
SUPPLIED INFORMATION	

LIST NAME, TITLE, AGENCY OF ANY OTHER GOVERNMENT INSPECTORS PRESENT DURING THE INSPECTION

FIRM NAME	CF NO.	INSPECTION DATE(S)

FIRM'S TRAINING PROGRAM

FOR LACF, ARE ALL OPERATORS OF THERMAL PROCESSING SYSTEMS AND CONTAINER CLOSURE INSPECTORS UNDER THE OPERATING SUPERVISION OF A PERSON WHO HAS ATTENDED AN APPROVED SCHOOL? *(See 108.35(g) and 113.10)*

☐ YES ☐ NO

FOR ACIDIFIED FOODS, ARE ALL PLANT PERSONNEL INVOLVED IN ACIDIFICATION, pH CONTROL, HEAT TREATMENT, OR OTHER CRITICAL FACTORS OF THE OPERATION, UNDER THE OPERATING SUPERVISION OF A PERSON WHO HAS ATTENDED AN APPROVED SCHOOL? *(See 108.25(f) and 114.10 for details.)* THE EFFECTIVE DATE OF THIS REQUIREMENT IS SEPTEMBER 16, 1980.

☐ YES ☐ NO

NAME OF OPERATOR	OPERATIONS SUPERVISED OR PERFORMED	SCHOOL ATTENDED	DATE OF CERTIFICATE

RAW MATERIALS

FOR LACF, HOW ARE INCOMING RAW MATERIALS AND INGREDIENTS SUSCEPTIBLE TO MICROBIOLOGICAL CONTAMINATION HANDLED? *(See 113.81(a))*

LIST ALL SOURCES OF EMPTY CANS, JARS AND POUCHES

CONTAINER TYPE	SUPPLIER/ADDRESS

DOES THE FIRM PERFORM ANY ACCEPTANCE EXAMINATIONS ON INCOMING CONTAINERS?

☐ YES ☐ NO

LIST SOURCES OF RAW AGRICULTURAL PRODUCTS AND PESTICIDE USAGE DATA

DESCRIBE STORAGE CONDITIONS FOR INCOMING RAW AGRICULTURAL PRODUCTS

GIVE WATER SOURCE(S), DATE AND RESULTS OF MOST RECENT TEST(S) *(Microbiological and chemical contaminants, if performed)*

GIVE IDENTITY AND LEVEL OF FOOD AND COLOR ADDITIVES USED

FIRM NAME	CF NO.	INSPECTION DATE(S)

LIST ANY PRESERVATIVES ADDED TO ACIDIFIED FOODS *(See 114.80(a)(1))*

WASHING AND SORTING

DESCRIBE WASHING AND SORTING OPERATIONS

BLANCHING

(Firm should avoid thermophilic growth temperatures, 122-131 degrees F. (See 113.81(b))

EQUIPMENT/PROCEDURES

HOW CONTROLLED, CHECKED

DESCRIBE WATER SOURCE *(If live steam contacts product, what boiler additives are used and are they on approved list? (See 21 CFR 173.310.)*

TIME/TEMPERATURE OF BLANCHING	INTERNAL TEMPERATURE OF FOOD AFTER BLANCHING

EMPTY CONTAINER HANDLING

(Caution: Any cans removed from the line for examination should not be returned since flanges could be damaged.)

CONDITION OF EQUIPMENT *(Wear, burrs, etc.)*

WHAT TYPE OF CONVEYOR SYSTEM IS USED FOR EMPTY CONTAINERS?

IF CABLE CONVEYOR, IS THE CABLE COATED?	IS CABLE ON ITS GUIDES THROUGHOUT CONVEYOR?
☐ YES ☐ NO	☐ YES ☐ NO
IS CABLE OPERATING SMOOTHLY?	IS CABLE CAUSING ANY WEAR ON CANS?
☐ YES ☐ NO	☐ YES ☐ NO
CONVEYOR SHUT-OFF SYSTEM TYPE?	IS CONVEYOR SHUT-OFF SYSTEM WORKING PROPERLY?
☐ AUTOMATIC ☐ MANUAL	☐ YES ☐ NO

IF FIRM REFORMS CANS, WHAT IS THE DEFECT RATE FROM FIRMS RECORDS?

FIRM NAME	CF NO.	INSPECTION DATE(S)

DOES FIRM KEEP RECORD OF TIN STOCK USED FOR EACH LOT OF FINISHED CANS? ☐ YES ☐ NO	ARE CAN FLANGES *(both ends)* FREE FROM DEFECTS? ☐ YES ☐ NO

DESCRIBE CONTAINER CLEANING METHOD

PREPARATION OF PACKING MEDIUM

GIVE FORMULA

GIVE TIME/TEMPERATURES OF PREPARATION AND HOLDING

IS EQUIPMENT ADEQUATELY CLEANED?

ACIDIFICATION AND WATER ACTIVITY CONTROL

FOR PARTIALLY ACIDIFIED *(above 4.6)* LACF PRODUCTS, HOW IS ACIDIFICATION PERFORMED AND CONTROLLED? *(See 113.81(e))*

FOR WATER ACTIVITY CONTROLLED LACF PRODUCTS, HOW IS THE WATER ACTIVITY SPECIFIED IN THE SCHEDULED PROCESS ACHIEVED AND CONTROLLED? *(See 113.81(f))*

FOR ACIDIFIED PRODUCTS, HOW IS ACIDIFICATION PERFORMED AND CONTROLLED? *(See 114.80(a)(1) through (a)(3))*

FILLING

GIVE METHOD(S) USED FOR EACH CONTAINER SIZE. *(See 113.81(c))*

GIVE EQUIPMENT MODEL(S)/MANUFACTURER(S)

IS EQUIPMENT ADEQUATELY CLEANED?

FIRM NAME	CF NO.	INSPECTION DATE(S)

FILLING (cont'd)

ARE THERE ANY PROBLEMS WITH PRODUCT OVERLAYING EDGES OF CONTAINERS?

HOW IS HEADSPACING CONTROLLED?

IS THERE ANY POTENTIAL FOR DAMAGE TO CAN FLANGES DUR FILLING/HEAD SPACING?

CONTROL OF CRITICAL FACTORS

(Per 113.40(a)(13), (b)(14), (c)(10), (d)(8), (e)(7), (f)(9), and (g)(4), critical factors specified in the scheduled processes for all retort types shall be measured and recorded at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. Critical factors should be measured and recorded at intervals not to exceed 15 minutes. See 113.40(h), and (i) for regulations dealing with flame sterilizer systems and thermally processed foods in which critical factors such as water activity are used in conjunction with thermal processing.)

CRITICAL FACTORS *(As applicable)*	FREQUENCY OF CHECKS AND RECORDING
MAXIMUM DRAINED WEIGHT	
MAXIMUM FILL WEIGHT	
pH	
MINIMUM NET WEIGHT	
PERCENT SOLIDS	
MINIMUM HEADSPACE *(Agitating retorts)*	
PRODUCT CONSISTENCY *(Agitating retorts)*	
MINIMUM CLOSING MACHINE VACUUM *(for vacuum packed products)*	
FOR RETORTABLE POUCHES: POUCH SIZE	
LIMITS OF VAPOR/AIR ENTRAPMENT	
RACKING CONFIGURATION: ORIENTATION OF POUCH	
POUCH THICKNESS RESTRICTION	
POUCH SEPARATION	
FLOW PASSAGE	
HEATING MEDIUM *(e.g., water, steam air, etc.)*	
CIRCULATION OF HEATING MEDIUM	
OTHER *(As specified in scheduled process)*	

FIRM NAME	CF NO.	INSPECTION DATE(S)

CLOSING

GIVE EQUIPMENT MODEL/MANUFACTURER/NUMBER OF SEAMER HEADS

DESCRIBE EQUIPMENT SANITATION AND MAINTENANCE

WHEN WERE THE CHUCK, ROLLERS, LIFTERS, BEARINGS, ETC. LAST REPLACED ACCORDING TO THE CLOSING MACHINE PREVENTIVE MAINTENANCE AND PARTS RECORDS?	ESTIMATED NUMBER OF CANS SEAMED SINCE LAST MAJOR OVERHAUL OF SEAMER

IF APPLICABLE, DESCRIBE "CLINCHING" OPERATION *(i.e., partial seaming operation sometimes performed prior to usual double seaming operation).*

WHAT IS THE METHOD OF HEADSPACE EXHAUST? *(See 113.81(d).*

IS THERE ANY POTENTIAL FOR CONTAINER DAMAGE *(especially seams)* DURING CLOSING OR DISCHARGE FROM CLOSING MACHINE?

HOW LONG MAY UNPROCESSED CONTAINERS BE HELD IN EVENT OF BREAKDOWN?

WHAT IS DISPOSITION IF TIME LIMITS ARE EXCEEDED?

DO CRATES, TRAYS, GONDOLAS, ETC. FOR HOLDING CONTAINERS FOR PROCESSING IN STEAM IN STILL REPORTS MEET THE REQUIREMENTS AND RECOMMENDATIONS OF 113.40(a)(9)?

HOW ARE CANS STACKED FOR PROCESSING? *(See 113.40(a)(9).)*

☐ HORIZONTAL ☐ VERTICAL ☐ RANDOM

IF PRODUCT IS STRATIFIED IN CONTAINERS *(e.g. whole leaf spinach, asparagus spears)* ARE THE CONTAINERS STACKED SO THE PLANE OF STRATIFICATION WILL BE VERTICAL DURING PROCESSING?

☐ YES ☐ NO, IF NO, HOW ARE CONTAINERS STACKED? _____

IS THERE ANY POTENTIAL FOR CONTAINER DAMAGE DUE TO OVERFILLING OF RETORT CRATES AND/OR STACKING OF OVER-FILLED CRATES?

CONTAINER CLOSURE CHECKS

(Per 113.60, visual and teardown double seam exams shall be performed at intervals of sufficient frequency to ensure proper closure and maintenance of seam integrity. Visual exams of double seams should be performed at intervals not to exceed 30 minutes; teardown exams should not exceed 4 hours. For acidified foods, see 114.80(a)(4)).

FOR CANS, HOW OFTEN ARE VISUAL AND TEARDOWN SEAM EXAMINATIONS *(including factory and reformed ends, if applicable)* PERFORMED AND RECORDED?

VISUALLY EXAMINE AT LEAST ONE CAN FROM EACH SEAMER HEAD FOR CAN SEAM DEFECTS SUCH AS CUTOVERS, DEAD HEADS, FALSE SEAMS, ETC. SEE ILLUSTRATIONS IN IOM EXHIBIT 530G. REPORT RESULTS:

FIRM NAME	CF NO.	INSPECTION DATE(S)

CONTAINER CLOSURE CHECKS (cont'd)

FOR JARS, WHAT IS THE METHOD AND FREQUENCY OF CLOSURE INTEGRITY MEASUREMENTS AND FREQUENCY OF RECORDING?

FOR POUCHES, WHAT IS THE METHOD AND FREQUENCY OF SEAL INTEGRITY MEASUREMENTS AND FREQUENCY OF RECORDING?

VISUALLY EXAMINE A REPRESENTATIVE NUMBER OF POUCHES FOR DEFECTS SUCH AS FOLDS, SEVERE WRINKLES, BLISTERS, AND TRAPPED PRODUCT IN SEALS. ALSO CHECK POUCHES FOR SEVERE DEFORMATION, GROSS OVERFILL, DELAMINATION AND LEAKS. REPORT RESULTS:

DESCRIBE THE FIRM'S COLD WATER VACUUM RECORDS FOR JARS UTILIZING VACUUM CLOSURES: *(See 113.60(a)(2))*

DO WRITTEN RECORDS OF LACF CONTAINER CLOSURE EXAMINATIONS *(see 113.60(a)(1) and 113.100(c))* INCLUDE THE FOLLOWING ITEMS *(Check blocks for included items.)*

☐ PRODUCT CODE ☐ DATE ☐ TIME OF EXAMINATION ☐ SEAM MEASUREMENTS PERFORMED

☐ CORRECTIVE ACTIONS TAKEN ☐ SIGNATURE OR INITIALS OF CLOSURE INSPECTOR AND REVIEWER

NOTE: Different measurements are required depending on the measurement system used. Check the blocks to indicate which measurements are recorded for the appropriate system.

MICROMETER

IS THIS METHOD USED? FOR EACH ITEM, 3 MEASUREMENTS, 120 DEGREES APART, EXCLUDING SIDE SEAM

☐ YES ☐ NO IF NO, DESCRIBE METHOD USED BELOW.

REQUIRED MEASUREMENTS

☐ COVER HOOK ☐ BODY HOOK ☐ WIDTH *(Length, Height)* ☐ TIGHTNESS *(Wrinkle)* ☐ THICKNESS

OPTIONAL MEASUREMENTS

☐ OVERLAP *(By calculation)* ☐ COUNTERSINK

SEAM SCOPE OR PROJECTOR

IS THIS METHOD USED?. FOR EACH ITEM, 2 MEASUREMENTS AT DIFFERENT LOCATIONS, EXCLUDING SIDE SEAM

☐ YES ☐ NO IF NO, DESCRIBE METHOD USED BELOW

REQUIRED MEASUREMENTS

☐ BODY HOOK ☐ OVERLAP ☐ TIGHTNESS *(Wrinkle)* ☐ THICKNESS *(by micrometer)*

OPTIONAL MEASUREMENTS

☐ WIDTH *(Length, Height)* ☐ COVER HOOK ☐ COUNTERSINK

CODES

EXPLAIN THE CODE SYSTEM

DOES THE CODE IDENTIFY THE FOLLOWING? *(See 113.60(c) and 114.80(b))* *(Check the blocks for those items identified by the code.)*

☐ PRODUCT ☐ YEAR ☐ DAY ☐ PACKING PERIOD ☐ ESTABLISHMENT WHERE PACKED

THERMAL PROCESSING ROOM OPERATIONS

ARE OPERATING PROCESSES AND VENTING PROCEDURES POSTED OR READILY AVAILABLE AS REQUIRED BY 113.87(a)?

☐ YES ☐ NO IF NO, WHERE ARE THEY KEPT?

FIRM NAME	CF NO.	INSPECTION DATE(S)

THERMAL PROCESSING ROOM OPERATIONS

DOES THE POSTED PROCESS AGREE WITH THE FILED PROCESS OR WITH AN OPERATIONAL PROCESS GREATER THAN THE FILED PROCESS? ☐ YES ☐ NO IF NO, EXPLAIN DIFFERENCES

IS RETORT TRAFFIC SUFFICIENTLY CONTROLLED TO PREVENT MIXUPS? *(See 113.87(b)).*
☐ YES ☐ NO IF NO, EXPLAIN TRAFFIC FLOW

LIST BRAND(S) OF HEAT SENSITIVE INDICATORS USED AND HOW ATTACHED. *(See 113.87(b))*

ARE VISUAL CHECKS OF HEAT SENSITIVE INDICATORS MADE AFTER RETORTING? ☐ YES ☐ NO	ARE THEY RECORDED? *(See 113.87(b))* ☐ YES ☐ NO

REPORT EXACT PROCEDURE FIRM USES TO DETERMINE INITIAL TEMPERATURE. *(See 113.87(c))*

FOR OPERATIONS USING WATER IN THE RETORT, WHAT PROVISIONS ARE MADE TO PREVENT WATER FROM LOWERING I.T.?

WHAT TIMING DEVICE(S) ARE USED TO TIME THE PROCESS AND WHEN WERE THEY LAST CHECKED FOR ACCURACY? *(See 113.87(d))*

DO CLOCK TIMES ON RECORDING THERMOMETER CHARTS CORRESPOND REASONABLY WITH TIMES ON WRITTEN PROCESSING RECORDS? *(See 113.87(e))* ☐ YES ☐ NO IF NO, EXPLAIN

REPORT PRESSURE AND ADEQUACY OF STEAM SOURCE. *(See 113.87(f))*

LIST THE NUMBER, SIZE AND TYPE OF ALL THERMAL PROCESSING SYSTEMS IN THE PLANT HERE. USE COPIES OF FORM FDA 3146a *(For processing in steam in still retorts)* OR BLANK SHEETS COVERING 21 CFR 113.40 REQUIREMENTS IN DETAIL *(for other retorts or processing systems)* TO REPORT THERMAL PROCESSING EQUIPMENT DATA.

FIRM NAME	CF NO.	INSPECTION DATE(S)

LIST YOUR ACTUAL THERMAL PROCESSING OPERATION OBSERVATIONS USING THESE OR OTHER APPROPRIATE HEADINGS

RETORT NO.	PRODUCT CODE	TIME STEAM ON	TIME/TEMP. VENT CLOSED	I. T.	TIME/TEMP. PROCESS START	RECORDER TEMP.	TIME PROCESS STOP	TIME/TEMP. SCHEDULED PROCESS

DESCRIBE ANY QUESTIONABLE PRACTICES OR OR DISAGREEMENT BETWEEN YOUR OBSERVATIONS AND FIRM'S RECORDS.

POST PROCESS HANDLING

IF CONTAINERS ARE WATER COOLED, WHAT IS THE SOURCE OF THE COOLING WATER?	WHAT IS THE CONCENTRATION OF CHLORINE?
DESCRIBE ANY OTHER WATER TREATMENT USED *(See 113.60(b))*	HOW OFTEN IS CHLORINE *(or other chemical used)* LEVEL CHECKED PER FIRM'S TESTING RECORDS AND YOUR OBSERVATIONS?

IF CONTAINERS ARE AIR COOLED, WHERE?

ARE AIR COOLING CONTAINERS PROTECTED FROM CONTAMINATION FROM EMPLOYEE GARMENTS, RODENTS, BIRDS, WET POROUS SURFACES SUCH AS WOOD CRATES, ETC.? ☐ YES ☐ NO IF NO, EXPLAIN.

IF CONTAINERS ARE COOLED UNDER PRESSURE, DESCRIBE AIR SUPPLY AND CONTROLS.

FIRM NAME	CF NO.	INSPECTION DATE(S)

POST PROCESS HANDLING (cont'd)

DESCRIBE METHOD AND TYPE OF EQUIPMENT USED FOR CRATE UNLOADING, CAN UNSCRAMBLING, LABELING, AUTOMATIC CASE-UP, ETC:

IS THERE ANY POTENTIAL FOR CONTAINER DAMAGE FROM ROUGH HANDLING OR CONTAMINATION FROM STANDING WATER, ROUGH SPOTS, BARBS, ETC. ON CONTAINER HANDLING SURFACES? *(See 113.60(d)* ☐ YES ☐ NO IF YES, REPORT THE TYPE, DEGREE AND FREQUENCY OF CONTAINER DEFECTS OR DAMAGE NOTED. DOCUMENT GROSS DEFECTS OR DAMAGE WITH PHOTOGRAPHS AND/OR SAMPLES. IF SAMPLES ARE COLLECTED, REPORT SAMPLE NUMBERS AND THE NUMBER OF CONTAINERS COLLECTED OUT OF THE TOTAL EXAMINED.

WHAT IS FIRM'S PROCEDURE IF CAN SEAM PROBLEMS ARE FOUND AFTER THERMAL PROCESSING?

WHAT FACILITIES/PROCEDURES ARE AVAILABLE FOR CLEANING AND SANITIZING ALL POST PROCESSING CONTAINER HANDLING EQUIPMENT?

ARE THERE WRITTEN CLEANING AND SANITIZING PROCEDURES AND ACCOMPLISHMENT RECORDS?

☐ YES ☐ NO

RECORD DATA ENTRIES

ARE ALL RECORD DATA ENTRIES MADE AT THE TIME THE ACTUAL OPERATION OCCURS? *(See 113.100(a)).*

☐ YES ☐ NO IF NO, DESCRIBE YOUR OBSERVATIONS.

RECORDS FOR LACF PRODUCTS

DO THERMAL PROCESSING RECORDS INCLUDE THE FOLLOWING ITEMS, AS REQUIRED BY 113.100? CHECK EACH ITEM WHICH IS INCLUDED ON THE RECORDS.

☐ PRODUCT ☐ CODE ☐ DATE ☐ RETORT NO. ☐ CONTAINER SIZE ☐ APPROXIMATE NO. OF CONTAINERS PER CODING INTERVAL

☐ INITIAL TEMPERATURE ☐ ACTUAL PROCESSING TIME ☐ MERCURY THERMOMETER READINGS

☐ RECORDING THERMOMETER READINGS ☐ APPROPRIATE SIGNATURE OR INITIALS

LIST OTHER APPROPRIATE PROCESSING DATA INCLUDED

FIRM NAME	CF NO.	INSPECTION DATE(S)

RECORDS FOR LACF PRODUCTS (cont'd)

DO RECORDS ALSO INCLUDE THE FOLLOWING ADDITIONAL ITEMS ALSO REQUIRED FOR SPECIFIC PROCESSING SYSTEMS? CHECK EACH ITEM WHICH IS INCLUDED IN THE RECORDS.

STILL RETORTS
- ☐ TIME STEAM ON
- ☐ TIME TEMPERATURE IS UP TO PROCESSING TEMPERATURE
- ☐ TIME STEAM OFF
- ☐ VENTING TIME AND TEMPERATURE TO WHICH VENTED

AGITATING RETORTS
- ☐ FUNCTIONING OF CONDENSATE BLEEDER
- ☐ RETORT SPEED

HYDROSTATIC RETORTS
- ☐ TEMPERATURE IN STEAM CHAMBER BETWEEN STEAM/WATER INTERFACE AND LOWEST CONTAINER POSITION
- ☐ SPEED OF CONTAINER CONVEYOR CHAIN
- ☐ TEMPERATURE NEAR TOP AND BOTTOM OF EACH HYDROSTATIC WATER LEG *(when the scheduled process specifies maintenance of a particular temperature in hydrostatic water legs)*

ASEPTIC SYSTEMS
- ☐ PRODUCT TEMPERATURE IN HOLDING TUBE OUTLET, AS INDICATED BY TEMPERATURE INDICATING DEVICE AND TEMPERATURE RECORDER
- ☐ PRODUCT TEMPERATURE IN FINAL HEATER OUTLET, AS INDICATED BY TEMPERATURE RECORDER-CONTROLLER
- ☐ DIFFERENTIAL PRESSURE AS INDICATED BY DIFFERENTIAL PRESSURE RECORDER–CONTROLLER *(if product-to-product regeneration is used)*
- ☐ PRODUCT FLOW RATE, AS DETERMINED BY METERING PUMP OR FILLING AND CLOSING RATE
- ☐ STERILIZATION MEDIA FLOW RATE AND/OR TEMPERATURE
- ☐ RETENTION TIME OF CONTAINERS, AND CLOSURES WHERE APPLICABLE, IN THE STERILIZING EQUIPMENT
- ☐ STERILIZATION CYCLE TIMES AND TEMPERATURES *(where batch system is used for container and/or closure sterilization)*

FLAME STERILIZERS
- ☐ CONTAINER CONVEYOR SPEED
- ☐ SURFACE TEMPERATURE AT THE BEGINNING AND THE END OF THE HOLDING PERIOD
- ☐ NATURE OF CONTAINER

SYSTEMS RELYING ON CRITICAL FACTORS, SUCH AS WATER ACTIVITY, WITH THERMAL PROCESSING
- ☐ PRODUCT FORMULATION
- ☐ RESULTS OF a_w DETERMINATIONS
- ☐ THERMAL PROCESS USED AND ASSOCIATED CRITICAL FACTORS
- ☐ OTHER CRITICAL FACTORS IN SCHEDULED PROCESS

ARE RECORDING THERMOMETER CHARTS IDENTIFIED WITH THE FOLLOWING? CHECK INCLUDED ITEMS. *(See 113.100(b))*
- ☐ DATE
- ☐ RETORT NUMBER
- ☐ APPROPRIATE SIGNATURE OR INITIALS

ARE ALL RECORDS REVIEWED WITHIN ONE WORKING DAY AFTER PROCESSING AND PRIOR TO RELEASE OF PRODUCT?
☐ YES ☐ NO IF NO, WHEN ARE THEY REVIEWED? _____

ARE THEY SIGNED OR INITIALED BY REVIEWER? ☐ YES ☐ NO

ARE ALL RECORDS RETAINED IN ACCORDANCE WITH 108.35(h) and 113.100(e)? ☐ YES ☐ NO IF NO, EXPLAIN

RECORDS FOR ACIDIFIED PRODUCTS

DO RECORDS INCLUDE THE FOLLOWING ITEMS REQUIRED BY 114.100? CHECK EACH ITEM WHICH IS INCLUDED IN THE RECORDS

- ☐ EXAMINATION OF RAW MATERIALS
- ☐ EXAMINATION OF PACKAGING MATERIALS
- ☐ EXAMINATIONS OF FINISHED PRODUCTS
- ☐ RECORDS OF SUPPLIERS GUARANTEES
- ☐ PRODUCT
- ☐ CONTAINER SIZE
- ☐ CODE
- ☐ DATE
- ☐ pH MEASUREMENTS
- ☐ OTHER CRITICAL FACTORS

ARE ALL APPROPRIATE RECORDS REVIEWED AND RETAINED FOR 3 YEARS AS REQUIRED BY 108.25(g) AND 114.100(e)?
☐ YES ☐ NO IF NO, EXPLAIN

SUMMARY OF RECORDS REVIEWED

LIST DATES OF RECORDS REVIEWED. *(See IOM Exhibit 645.2a)*

FIRM NAME	CF NO.	INSPECTION DATE(S)

PROCESSING DEVIATIONS

DOES THE FIRM MAINTAIN A SEPARATE FILE (OR LOG) OF PROCESSING DEVIATIONS, AS REQUIRED BY 113.89 AND 114.100(C)?

☐ YES ☐ NO

IF PROCESSING DEVIATIONS DID OCCUR, WHAT ACTION DID THE FIRM TAKE IN EACH CASE? (SET ASIDE AND HOLD? REPROCESS? DESTROY? EVALUATE?) *(See 113.89 and 114.89)* REPORT FINDINGS BELOW

NOTE: PROCESSING DEVIATIONS INCLUDE FAILURE TO MAINTAIN CRITICAL FACTORS WITHIN ESTABLISHED LIMITS; e.g. MAXIMUM RATIO OF DRAINED WEIGHT TO NET WEIGHT FOR SPINACH, MAXIMUM FILL WEIGHT AND METHOD OF FILL FOR MUSHROOMS; ETC.

FIRM NAME	CF NO.	INSPECTION DATE(S)

WAREHOUSING

HOW ARE FINISHED CONTAINERS PROTECTED FROM CONTAMINATION FROM WATER, BIRDS, RODENTS, ETC.?

DOES THE FIRM INCUBATE LOTS OR PORTIONS OF LOTS PRIOR TO DISTRIBUTION? IF YES, EXPLAIN THE PRACTICE IN DETAIL

DETAIL ANY EVIDENCE OF SPOILAGE OR ABNORMAL CONTAINERS IN THE WAREHOUSE AREA BY CODE LOT NUMBER *(Examine any suspect codes identified through record review. If no lots are suspect randomly select several codes for warehouse examination.)* REVIEW RECORDS FOR ANY ABNORMAL CODES IDENTIFIED THROUGH WAREHOUSE INSPECTION.

FOR EXAMINED RETORTED POUCHES, DETAIL ANY FINDINGS OF SEAL DEFECTS SUCH AS FOLDS, SEVERE WRINKLES, BLISTERS, AND TRAPPED PRODUCT. ALSO REPORT FINDINGS OF SEVERE DEFORMATION, GROSS OVERFILL, DELAMINATION, LEAKS, AND EXCESSIVE SEAL CREEP AND DISTORTION WHICH COULD INDICATE INADEQUATE CONTROL OF PRESSURE COOLING.

FIRM NAME	CF NO.	INSPECTION DATE(S)

COMPLAINT FILE REVIEW

REPORT DETAILS OF ANY SIGNIFICANT COMPLAINTS, ESPECIALLY ANY COMPLAINTS SUGGESTIVE OF UNDERPROCESSING, SUCH AS ILLNESS OR ABNORMAL CANS.

RECALL PROCEDURES

DOES THE FIRM HAVE A WRITTEN RECALL PROCEDURE WHICH COMPLIES WITH THE REQUIREMENTS OF 108.25(e) OR 108.35(f)?

☐ YES ☐ NO IF NO, EXPLAIN

DOES THE FIRM MAINTAIN INITIAL DISTRIBUTION RECORDS AS REQUIRED BY 113.100(d) AND 114.100(d)? ☐ YES ☐ NO

IF NO, EXPLAIN

PROMOTION AND DISTRIBUTION

SEE IOM 592.31(m) FOR REQUIRED INFORMATION

REFUSALS

GIVE DETAILS OF ALL REFUSALS

SAMPLES

LIST SAMPLE NUMBER(S) WITH PRODUCT(S) COLLECTED

FIRM NAME	CF NO.	INSPECTION DATE(S)

EXHIBITS

LIST EXHIBITS

DISCUSSION WITH MANAGEMENT

REPORT PERSONS (NAME AND TITLE) WITH WHOM FDA-483 AND OTHER FINDINGS WERE DISCUSSED. LIST ALL RECOMMENDATIONS, WARNINGS, OR SUGGESTIONS GIVEN OR MADE TO MANAGEMENT AND REPORT MANAGEMENT'S RESPONSE.

SIGNATURE OF INVESTIGATOR

SIGNATURE OF INVESTIGATOR

Introduction

The aseptic processing and packaging of shelf stable products in hermetically sealed containers provides the food industry with an alternative means to thermally preserve products for nonrefrigerated distribution. The Food Safety and Inspection Service (FSIS) recognizes the potential of aseptic processing of meat and poultry products in federally inspected establishments and, therefore, makes the attached documents available.

I. FSIS Guidelines for the Evaluation of Proposed Aseptic Processing and Packaging Systems.

II. Guideline for the Preparation of Partial Quality Control (PQC) Programs for Aseptic Processing and Packaging Systems.

These documents are supplemental to the Meat and Poultry Inspection Regulations. In order for a federally inspected meat or poultry establishment to aseptically process and package food products for entry into commerce; the establishment personnel must first submit: (1) an "acceptable" proposal to FSIS and (2) an "acceptable" Partial Quality Control (PQC) program for the operation and maintenance of the accepted system.

Inquiries concerning these documents or requests for additional copies should be made to:

Aseptic Processing and Packaging
Systems Committee, Chairman
Meat and Poultry Inspection
Technical Services
FSIS, USDA, Room 2168-S
Washington, DC 20250
(202) 447-7386

Summary of Review and Acceptance Procedures

The following procedures are recommended for the most expeditious review and acceptance of aseptic processing and packaging systems.

A. FSIS encourages establishment personnel to carefully review the guidelines prior to the purchase and/or construction of any aseptic equipment. After reviewing the guidelines, establishment personnel should then provide FSIS with the information listed in Section 1--Review and Acceptance of Equipment. Establishment personnel should note that the guidelines for piping structures require a verification that all internal joints are smooth, continuous, and free of crevices. The method for verifying this requirement should be stated in the proposal.

If the proposed construction of equipment meets all applicable requirements, the Equipment Branch of the Facilities, Equipment, and Sanitation Division (FESD), will issue written authorization for the establishment to produce experimental product.

B. After receipt of this initial authorization, an establishment may construct the aseptic processing and packaging system. Test product may then be produced in the completed system for the purpose of developing the procedures detailed in Section III--Process Controls. Any food product produced under these conditions, unless otherwise processed separately to insure wholesomeness, may not be released as federally inspected product.

Based upon the testing, establishment personnel should prepare and submit:

1. Performance testing protocol and results on containers.

2. Pre-production testing protocol and results on the aseptic system covering package sterilization, equipment sterilization, and product sterilization.

3. A PQC program addressing aseptic system operations and controls. This PQC program must address the criteria outlined in the guidelines.

In addition, any changes from the proposed equipment (from that which was initially submitted) must be reported. Verification that all joints are smooth, continuous, and free of crevices must also be submitted at this time.

If the pre-production testing, packaging materials, and proposed PQC program are acceptable, FSIS will issue written authorization for the production of commercial product. The Equipment Branch will also issue written authorization for a 90-day experimental use to evaluate the sanitary design and construction of the equipment.

C. Upon receipt of these written authorizations, an establishment may begin commercial production of aseptically processed and packaged product. Upon expiration of the 90-day experimental use period, the FSIS inspector will file the routine inspector's report. If this report is positive, the Equipment Branch will issue a final acceptance letter for the equipment.

Any modifications to an accepted system and/or an accepted PQC program must be submitted, in writing, to FSIS before any changes are incorporated.

FSIS Guidelines for the Evaluation of Proposed Aseptic Processing and Packaging Systems

The Food Safety and Inspection Service (FSIS) defines aseptic processing and packaging as the filling of a shelf stable product (commercially sterile) into sterilized containers followed by hermetical sealing with a sterilized closure in an environment free of microorganisms.

The following guidelines are for designing and evaluating aseptic processing systems. These guidelines define the minimum requirements for equipment and processing control procedures an establishment must address in a proposed program submitted for Agency approval. These guidelines are based upon current knowledge of aseptic processing and were written to ensure the production of only safe, wholesome food products in accepted systems. However, FSIS is aware that innovations in aseptic processing are continuously being developed and refined. Therefore, FSIS encourages establishments to propose any process(es) which they believe ensures the production of safe, wholesome product even though this method(s) may not conform to the specific guideline criteria. FSIS will review and evaluate any such variations accordingly.

An establishment's proposal must include all formulations, process controls, equipment arrangements, and operating schedules for any and all aseptically processed and packaged product to be produced within that establishment. Any modifications to an approved program for aseptic processing must be submitted, in writing, to the Agency before any changes are incorporated.

DEFINITIONS

1. Batch sterilization - The process in which formulated product, or a portion thereof, is held stationary (with or without agitation) in a product sterilizer for the purposes of heating and holding product for at least the time-temperature combination necessary to achieve a state of shelf stability.

2. Commercial sterility (of equipment and containers) - The condition achieved and maintained by application of heat, or other appropriate treatment, which renders equipment and containers free of microorganisms capable of growing in shelf stable product at temperatures at which the finished product is likely to be held during distribution and storage.

3. Continuous flow sterilization - The process in which a formulated, heated product, or a portion thereof, is maintained at or above a minimum temperature for a given time during the continuous flow of product to attain a state of shelf stability.

4. Process schedule - The minimum time-temperature combination necessary to achieve shelf stability for any given product when all critical factors are taken into account. (Examples of critical factors include, but are not limited to, flow rate, viscosity, particulate size and formulation.)

5. Product heater - The equipment used to heat product to a temperature necessary to begin process schedule delivery.

6. Product-to-product regenerator (heat exchanger) - Any equipment designed such that enclosed, sterile product is transported adjacent to, but completely separated by a common barrier from, unsterile product (or any other unsterile medium) for the purpose of heat exchange or any other reason.

7. Shelf Stable - The condition achieved by application of heat, either sufficient alone or in combination with other ingredients and/or treatments, to render the finished product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50° F. or 10° C.) which the product is likely to be held during distribution and storage. (For aseptically processed and packaged low acid foods and acidified low acid foods, FSIS considers the terms shelf stable and commercially sterile to be synonymous.)

I. REVIEW AND ACCEPTANCE OF EQUIPMENT

All equipment intended for use in an aseptic processing system must be reviewed and evaluated by the Equipment Branch; Facilities, Equipment, and Sanitation Division (FESD); Meat and Poultry Inspection Technical Services (MPITS). The review of each component piece of equipment and the integration of these components into a single aseptic system will be made on a custom basis only. Therefore, any commercially available, accepted equipment will not necessarily be listed in the MPI-2--Accepted Meat and Poultry Equipment. The Equipment Branch, however, will maintain a file of accepted aseptic processing equipment so that "common" component pieces need not be repetitively evaluated except for the manner in which the equipment will be combined with other component pieces. The materials necessary for the Equipment Branch review are listed as follows:

(1) Drawings clearly illustrating the main construction features of each component piece of equipment.

(2) A parts material list correlated to each drawing that shows the material used for each part.

(3) A brief description of the intended function and mode of operation for each component piece of equipment.

(4) A proposed facility layout identifying the relative locations of all equipment and piping structures used in the aseptic processing system. Depending upon the magnitude of modification, extensive facility changes may require review and approval by the Facilities Branch of FESD, MPITS. (Example: The placement of equipment within a processing area must provide adequate space for proper sanitation and inspection.)

Note: The Freedom of Information Act, 5 U.S.C. 552, provides that information in the possession of the Federal Government must be made public upon request unless certain specified exemptions apply. One of these exemptions covers "trade secrets and commercial or financial information . . ." (5 U.S.C. 552(b)(4)).

In order to protect the legitimate commercial interests of those submitting information to the Equipment Branch, the submitting party should identify all material considered to be either a trade secret or confidential commercial or financial information and supply a statement explaining why it is so considered. While this procedure will not guarantee that the information will be exempt from disclosure, it will ensure that the wishes of the submitting party will be given consideration in any decision reached.

When FSIS receives a request for material identified as a trade secret or confidential commercial or financial information, the Agency will notify the submitting party before disclosing the information.

Questions concerning the Freedom of Information Act and its effect on the procedures of the Agency should be addressed to:

Freedom of Information Act Coordinator
Food Safety and Inspection Service
Room 334-E
U.S. Department of Agriculture
Washington, DC 20250

Aseptic equipment will be evaluated using essentially the same criteria as that applied to other equipment although, due to the unique aspects of aseptic processing, the Agency reserves the right to apply any "special" requirements deemed necessary to assure the production of safe, wholesome product. These special requirements will vary on a case-by-case basis depending on the proposed aseptic methodology. Establishments are advised to submit proposals prior to the construction or purchase of any equipment.

Several general requirements are applicable to all aseptic processing systems. These are:

A. Piping Structures - The piping structures used to transport product must be constructed of stainless steel and must be suitably supported. (The Agency will consider materials other than stainless steel if such proposed materials are of a sanitary design and capable of withstanding the temperatures and pressures of an aseptic processing system.)

1. Joints - Sections of stainless steel pipes joined by welding or any other means must result in an internal joint which is smooth, continuous, and free of crevices. In the submitted drawings, an establishment should indicate the areas in which such welds or solid joints are anticipated. After the aseptic processing system is tentatively accepted and the equipment is constructed, the establishment must provide verification that all joints are indeed smooth, continuous, and free of crevices. The method of verification must be included in the initial proposal.

2. Hold Tubes - The hold tubes shall be designed so that no portion of the tube between the product inlet and the product outlet can be heated, and it must be sloped upward at least 0.25 inch per foot of piping. The hold tube will be considered to end (outlet) at the point where (a) the upward slope of the piping ceases to be at least 0.25 inch per foot of piping, (b) the final temperature recording device is located, or (c) the piping structure merges into another component piece of equipment. The establishment must indicate on the submitted drawings where the end of the hold tube (outlet) is located.

   The hold tube must be located where fluctuations in ambient temperatures will be minimal.

B. Temperature Indicator, Recorder, and/or Controller Devices - Temperature indicating devices (e.g., thermocouple systems, mercury-in-glass thermometers) shall have divisions which are easily readable to 1° F. Mercury-in-glass thermometers shall have a temperature range which does not exceed 17° F. per inch of graduated scale. Temperature recording devices shall have graduations that do not exceed 2° F. within a range of 10° F. of the processing temperature. Each chart shall have a working scale of not more than 55° F. per inch within a range of 20° F. of the desired product sterilization temperature. The temperature recording device located at the hold tube outlet must provide a continuous tracing or recording. At other locations, devices which do not provide a continuous tracing or recording will be considered provided the time interval does not exceed thirty seconds. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

   1a. Product Heater (Continuous Flow) - In the facility layout, an establishment must clearly show the location of a device(s) which controls and records (at appropriate intervals) the temperature of the heated product upon immediate exit from the product heater. The probe must be positioned to minimize the internal obstruction.

   b. Hold Tubes - When hold tubes are used, the probe of an automatic temperature recording device must be located at the hold tube outlet. In addition, a separate visual temperature indicator probe must be located in close proximity to the automatic temperature recording device probe. The probes for both devices must be located so that (a) the conductivity of the piping structure does not interfere with the accurate determination of product temperature, (b) the internal obstruction created by the probes is minimized, and (c) neither probe is located past the point where the upward slope of the hold tube falls to less than 0.25 inch per foot of piping.

2. Product Sterilizer (Batch Type) - In the facility layout, an establishment must clearly show the location of a device(s) which controls and records (at appropriate intervals) the temperature of the heated product in the product sterilizer. In addition, a separate visual temperature indicator must be located in close proximity to the automatic temperature recording device. The product sterilizer must be designed and operated so that both temperature probes can be properly located to accurately and precisely measure the product temperature at all times during process schedule delivery.

C. Differential Pressure Recorder/Controller - Differential pressure recorders must have a scale which is easily and accurately readable. Graduations must not exceed 0.14 kg/cm^2 (2 lb/in^2) on a working scale of 1.4 kg/cm^2 (20 lb/in^2). However, in systems where the operating differential pressure exceeds 1.4 kg/cm^2 (20 lb/in^2), alternative scale parameters will be considered.

1. Product-to-Product Regenerators - If the design of the proposed aseptic processing system is such that enclosed, sterile product will be transported adjacent to, but completely separated by a common barrier from, an unsterile medium for the purpose of heat exchange or any other reason, a differential pressure recorder(s) must be employed. An adequate number of sensors must be used to monitor and record the difference between the lowest sterile product pressure and the highest unsterile medium pressure. The system must be designed so that the pressure in the sterile piping is at least one pound per square inch greater than the pressure exerted on the unsterile medium. This pressure difference must be maintained at all times during system sterilization and processing.

D. Pumps - The flow of product from the product heater through the hold tubes must be accomplished by mechanical pumping action or other appropriate means, i.e., gravity flow through the hold tubes is strictly prohibited.

In continuous flow systems, the back pressure in the hold tubes must be properly controlled.

E. Valves - Any valves used on either the sterile or unsterile sides, whether automatic or manually operated, must be presented for review.

F. Obstructions and Quick Disconnect Mechanisms - Internal obstructions in the sterile piping system should be kept to a minimum. In those cases where internal obstructions are necessary (e.g., temperature probe inserts), piping systems must be equipped with accepted, quick-disconnect mechanisms to facilitate the inspection of the involved pieces. The establishment may, however, offer alternative methods of

inspection for the Agency's consideration. The facility layout should clearly indicate the location of all breaks in the system. Any break in the sterile piping during operation requires resterilization.

G. Diversionary Systems - Any component equipment designed to alter the continuous flow of product is considered to be a diversionary system. Such systems may be included for either emergency or routine operational procedures. However, such systems must be designed so that product can be (1) maintained in a sterile state, (2) channeled back to the unsterile side for reprocessing, or (3) channeled out of the aseptic processing system and discarded or used for some other acceptable purpose.

If used, aseptic surge tanks must meet all of the requirements for diversionary systems. The establishment should provide detailed drawings illustrating the design, function, and operation of surge tanks.

H. Steam Seals - Product coolers, aseptic surge tanks, or any other equipment downstream from the hold tube, with rotating or reciprocating shafts, or other such points, are subject to potential entry of microorganisms into the product. Such locations in the system shall be equipped with steam seals or other effective barriers at the potential access points. The operator must monitor the performance of the seals or barriers during operations.

I. Packaging Units - Packaging units must be designed so that (1) the designated sterile zone can be sterilized prior to processing, (2) packaging material can be sterilized, (3) the operation produces a shelf stable, packaged product, and (4) all presterilizing and sterilizing functions are controllable to the extent necessary. In the proposal, an establishment should identify the positions and types of monitoring control devices that will verify the proper function of the presterilizing and sterilizing features.

For those packaging units designed to sterilize packaging material, in whole or part, by immersion in a liquid bactericide, an automatic sensing device must be included to ensure an adequate level of the bactericide.

Air and/or gasses used in the designated sterile zone and in contact with food product, packaging material, and/or sterile surfaces must be (1) FDA approved for the intended use, and (2) filtered and incinerated or filtered through at least two separate systems each capable of producing sterile air. Air used in areas other than the designated sterile zone must be filtered.

Ultraviolet light, water, and/or steam may also be employed as methods for presterilization and/or sterilization.

1. Bactericidal Spraying, Fogging and Immersion - Bactericides may be used for presterilization of the designated sterile zone and also for the in-process sterilization of packaging material

(provided the bactericide is FDA approved at the intended levels). Spray and fogging systems must be designed to provide a uniform, well dispersed application. Packaging units must be designed so that bactericide vapors can be reasonably contained and subsequently exhausted out of the packaging unit and away from the processing area.

2. Introduction of Packaging Material - The packaging unit must be designed so that the entries for packaging material and the exit for packaged, shelf stable product are minimized to the extent possible. The packaging unit must be designed so that a continuous positive air flow from these openings will constantly occur during presterilization and operation. Belts and/or other components designed to move in and out of the designated sterile zone must be resterilized before reentry into the designated sterile zone.

3. Sensors - Packaging units must be equipped with sensing devices that eliminate the possibility of the filling of cells for which packaging material has not been supplied.

J. Warning Signs and Control Devices - Devices used to monitor and/or control the temperature or pressure of the sterilization process, and devices on all process controls of the packaging units must be protected from the possibility of unauthorized changes. Conveyor speed of the packaging unit may be considered a process control since the involved timing sequence may affect the sterilization process. A lock, or a notice (warning sign) from management posted at or near each device to warn that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes. The facility layout should show the location of warning signs. An exhibit of the warning sign should also be provided.

II. PACKAGING MATERIALS AND CONTAINERS*

Packaging materials or containers intended for use in aseptic systems must be composed of FDA approved components. FDA approval must be demonstrated by a guaranty or a statement of assurance from the supplier as stated in 9 CFR 317.20, 320.1, 381.44, and 381.175. Alternatively, the supplier or processing establishment may obtain written verification of the basis for any such guaranty from:

Compounds and Packaging Section
Food Ingredient Assessment Division
Science, FSIS, USDA
Bldg. 306
Beltsville, MD 20705

*Note: The information in this section as well as most of the information in Sections III and IV would be included in the PQC program. See guidelines for preparing PQC programs.

In addition, the Agency must have assurance that the packaging system, which includes the immediate container and all auxiliary packaging such as overcartons, cases, etc., can adequately ensure that the immediate container retains its hermetic condition during shipping and distribution. Agency guidelines covering the testing of semirigid and flexible containers are described in:

Test Cycles For Small Size Semirigid Containers - August 1982
Test Cycles for Small Size Flexible Retortable Pouches - June 1982

Copies of these documents are available from:

Canned Products Branch
Processed Products Inspection Division
Meat and Poultry Inspection Technical Services
FSIS, USDA
Room 2158-S
Washington, DC 20250
(202) 447-3723

III. PROCESS CONTROLS

A. Personnel - All operators of aseptic processing and packaging systems must be under the operating supervision of a person who has attended and satisfactorily completed an FDA approved "Better Process Control School in Canning."

The locks and/or warning signs required in close proximity to all control points (controllers, adjustment devices, and indicators for pressure, temperature, etc.) are intended to prohibit the adjustment of equipment by any individuals other than those authorized in the proposal submitted to FSIS. In addition, any routine alteration to the system (e.g., placement of additional hold tubes) must be (1) detailed in the establishment's proposal and (2) must be directly supervised by authorized personnel during operation.

B. Lot Control - The establishment must detail the procedure for which product identity will be maintained from the point of sterilization, through packaging and incubation, and as far through marketing distribution as is possible. In no event shall a lot be identified as a portion of production which exceeds a single day's production.

The purpose of the lot designation and control is to ensure the establishment's continuous capability to identify and segregate any product for which shelf stability is even slightly questionable.

Appropriate recording sheets for lot identification and control must be included as exhibits in the establishment's proposal. The authorized personnel listed for Section III-A should be responsible for the identification and recording of lot designations.

C. Cleaning - The establishment must detail the procedure by which the aseptic processing and packaging equipment will be cleaned, sanitized, and inspected by establishment employees. Such cleaning may be accomplished by breakdown of the equipment and/or cleaning in place. The establishment must detail the cleaning schedule and the type and dilution strength of the cleaning compounds.

Cleaning of the aseptic processing system must be adequate to ensure that all product debris is removed from the interior and exterior of all equipment and piping structures. (FSIS reserves the authority to require dismantling of equipment to any degree deemed necessary to assure proper, adequate cleaning of all internal surfaces.)

Appropriate recording sheets for dilutions, times, temperatures, and/or pressures of all cleaning substances and procedures must be included as an exhibit in the establishment's proposal. The authorized personnel listed for Section III-A should be responsible for verifying that adequate cleaning procedures have been employed and recorded.

D. Presterilization - The establishment must describe how the aseptic processing and packaging equipment will be presterilized immediately before production. The establishment must also detail how, following presterilization, the initial product introduced into the processing system will be prevented from cooking onto the internal surfaces of the equipment.

Appropriate recording sheets for times, temperatures, and/or pressures of all presterilizing treatments must be included as an exhibit in the establishment's proposal. The authorized personnel listed for Section III-A should be responsible for verifying that presterilizing procedures have been employed and recorded.

E. In-Process Controls - The procedure used to achieve shelf stability must be detailed for each line of product to be aseptically processed. Furthermore, the changeover from the sterilizing medium to product and the changeover from one product to another product must be detailed.

1. Formulation - The establishment should provide a general description of the formulation (product preparation) for each type of product intended to be aseptically processed. The formulation must meet all requirements of the product's approved label.

   The method in which the formulated product is introduced into the product heater must be addressed in the establishment's proposal. An establishment must specifically detail how the formulated product will be kept in a uniform mixture throughout the process up to and including packaging.

2. Product Sterilization - The establishment must identify the time/temperature combination necessary to achieve shelf stability for each product intended to be aseptically processed. For continuous flow systems, the flow properties of the formulated product can be included in this assessment. Unless otherwise documented, flow characteristics will be considered laminar and, therefore, the hold time/temperature must reflect a sterilization process which is targeted to achieve shelf stability of the fastest flowing particle. Only the time that product is flowing through the hold tube (continuous flow systems) may be considered for the time component of the sterilization process unless (a) product heater control is proven by records to be precisely controlled, (b) process delivery is proven by inoculated packs using spores of known heat resistance, and (c) the controlled process is verified by a processing authority. Records of this verification must be permanently retained.

   In the proposal, an establishment must show how sterilization of packaging material is achieved and maintained.

3. Flow Diversions, Emergency Systems, and Handling of Process Deviations - The establishment must detail the procedure to be used to identify, segregate, and control product which failed to achieve the hold time/temperature necessary to result in shelf stability. The establishment must also detail the procedure for handling process deviations according to either (a) MPI Bulletin 79-45 (May, 1979) or (b) a separate, approved PQC program.

   In addition, the establishment must identify the procedures (a) to return the system back to one of shelf stable product manufacture and to (b) prevent the "cooking on" of product onto the internal surfaces left voided by a diversion.

4. Equipment Calibration - All temperature indicating and differential pressure recorder devices must be tested for accuracy against a known accurate standard at the time of installation and at least every six months thereafter. Each device must have a tag, seal, or other means of identity which exhibits the date that the device was last tested for accuracy.

   Temperature indicating devices shall be the reference instrument for indicating the processing temperature(s). Temperature charts shall be adjusted to agree as nearly as possible, but in no event higher than, a known accurate temperature indicating device.

   Appropriate recording sheets for equipment calibration must be included as an exhibit in the establishment's proposal. The authorized personnel listed in Section III-A must be responsible for the testing and recording of temperature indicating/recording and differential pressure recorder/controller devices.

IV. TESTING PROCEDURES

Testing procedures include both pretesting and continuous monitoring of the aseptic processing system. Pretesting is defined as tests conducted on the system and/or test product after the equipment is installed in its final design but before any commercial product is produced for marketing purposes. In-process testing or monitoring is designed to assure that, after commercial production begins, all product intended for marketing will comply with all applicable regulations.

A. System Pretesting - The establishment must submit a procedure and test results which demonstrate that only shelf stable product will be produced and packaged within an aseptic processing system. This microbiological testing must be conducted on a pretest basis, i.e., the test methodology and subsequent results must be submitted to and evaluated by FSIS before any commercial production begins. The establishment should identify the types and numbers of spores used for all microbiological tests. The spore types selected for testing should be those which are resistant to the involved sterilization techniques. The calibrated spore resistance (D value) must be included. (An outside laboratory may calibrate the spore resistance and submit this information directly to FSIS. FSIS considers this information to be proprietary.)

The establishment should address the following tests:

1. Presterilization of equipment - The establishment must design a testing procedure which demonstrates that the proposed presterilization treatment(s) of the equipment is an effective means of sterilizing the designated sterile zone.

2. Packaging material - The establishment must design a testing procedure which demonstrates that the proposed sterilization treatment(s) is an effective means of rendering all packaging materials sterile.

3. Product sterilization - The establishment must provide a mathematical process design which proves that the hold time/temperature treatment for each formulated product is an effective means of rendering the involved product safe and stable. Inoculated pack studies should also be given consideration for confirmation of the mathematical process design.

B. Bactericidal Residues - When bactericides are used for the purposes of presterilizing any portions of the system and/or for sterilizing packaging material, the establishment must propose an acceptable method for the daily preoperational testing and in-process monitoring of the levels of bactericide remaining in the sealed container. Testing procedures for determining concentration of bactericides in solution must also be provided.

The establishment must detail the chemical analysis procedure used to determine the involved bactericidal residue(s). Testing should be conducted at a frequency sufficient to offset the anticipated variability of production and the involved chemical analysis procedure. It is recommended that an establishment conduct multiple analyses of individual sample units in order to demonstrate the anticipated variability.

The establishment must detail the procedure to be used for adjusting the packaging unit, etc. when unacceptable conditions are detected. Appropriate recording sheets for lot identification and control of in-process testing must be included as an exhibit in the establishment's proposal. The authorized personnel listed in III-A must be responsible for the testing and recording of chemical analysis results. An establishment may also include provisions for the "expanded" testing of lots suspected to contain unacceptable levels of a bactericide.

C. Package Testing - The establishment must detail the procedures to be used to assure that product is properly filled and sealed in the packaging unit. The establishment must propose appropriate procedures and descriptions to ensure that each individual container is free from the following defects before shipment:

1. Improper closure or seal
2. Delamination of package
3. Overfill
4. Leaker
5. Swollen or blown
6. Severely damaged
7. Soiled or stained
8. Other (specified)

If statistical sampling is used, the establishment must detail (a) the method for random sampling, (b) the sampling frequency, (c) the sample size, (d) the examination procedure, and (e) the acceptance criteria.

Appropriate recording sheets for lot identification and control must be included as an exhibit in the establishment's proposal. The authorized personnel listed for III-A must be responsible for the evaluation of package integrity and the subsequent recording of packaging defects.

D. Product Testing - An establishment may elect to routinely perform sterility tests on sealed, packaged product. If used, this testing procedure should be detailed in the establishment's proposal. In the

event of positive findings, such testing may result in the retention of product. However, such testing cannot replace any other testing required by the Agency.

E. Incubation - The establishment must detail the procedure for which representative samples from each lot of product will be selected and incubated for assurance of shelf stability. The frequency of such sampling and the holding times and temperature must be consistent with the appropriate USDA regulations.

V. FSIS ORGANIZATIONAL CONTACTS AND PUBLICATIONS

The evaluation and acceptance of aseptic processing and packaging systems involves various areas of responsibility within the Food Safety and Inspection Service (FSIS). Organizational contacts for each area of responsibility, along with relevant publications, are as follows:

1. Equipment Acceptance

Equipment Branch
Facilities, Equipment, and Sanitation Division
Meat and Poultry Inspection Technical Services
FSIS, USDA-S Room 2168
Washington, DC 20250
(202) 447-7386

Relevant publication - MPI-2, Accepted Meat and Poultry Equipment

2. Labeling

Standards and Labeling Division
Meat and Poultry Inspection Technical Services
FSIS, USDA
Annex Building, Room 204
Washington, DC 20250
(202) 447-6042

3. Packaging Material

a. Approval of Chemical Compounds (voluntary)

Compounds and Packaging Section
Product Safety Branch
Food Ingredient Assessment Division
Science, FSIS, USDA
Building 306
Beltsville, MD 20705
(301) 344-2566

b. Package Integrity

Canned Products Branch
Processed Products Inspection Division
Meat and Poultry Inspection Technical Services
FSIS, USDA-S, Room 2153
Washington, DC 20250
(202) 447-3723

Relevant publications - Test Cycles For Small Size Semirigid Containers - August 1982
Test Cycles for Small Size Flexible Retortable Pouches - June 1982

4. In-Process Controls and Testing Procedures

Canned Products Branch
Processed Products Inspection Division
Meat and Poultry Inspection
Technical Services
FSIS, USDA-S, Room 2153
Washington, DC 20250
(202) 447-3723

Relevant publications -

(a) MPI Bulletin 75-4; January 2, 1975
Flexible or Semirigid Retortable Packages

(b) MPI Bulletin 79-45; May 10, 1979
Abnormal Cans and Process Deviations

(c) Quality Control (QC) Guidelines for Handling Process Deviations

Guidelines for the Preparation of
Partial Quality Control (PQC) Programs for Aseptic
Processing and Packaging Systems

Quality Control Program Code 255

I. COVER LETTER PER REGULATION 318.4(d) OR 381.145(d).

A cover letter transmitting a proposed program must include the following information:

- o Establishment official responsible, official company signature, name of company and establishment number(s).
- o Objective of the program.
- o All data and information generated will be maintained for at least ____ years.
- o Records available to Department personnel.
- o Number of employees.
- o Number of Quality Control employees.

II. INTRODUCTION

A. Scope of program.

B. General description of processing system, including sterilization methods.

C. General description of packaging system, including sterilization methods.

III. PROGRAM CONTENT

A. Packaging materials and food contact concerns.

1. Letters of guarantees from manufacturers that materials comply with 21 CFR.
2. Package performance (reference approvals from the Processed Products Inspection Division/MPITS/FSIS).
3. Reference letters of acceptance from the Facilities, Equipment and Sanitation Division/MPITS/FSIS.
4. List sterilants and other chemicals used. Discuss the significance of any indirect additives. If steam and/or water is used, discuss how potability is assured.

B. Product information.

1. List of products to be packed.
2. Container dimensions and net weights.
3. Product formulas.
4. Product preparation procedures.

C. Aseptic equipment.

1. Instrument calibration - frequency and procedures.

a. Temperature indicators.
b. Recording devices (temp., conveyor speed, air flow rates, pressures and the like).
c. Controllers (air, steam, back pressure and the like).
d. Pump speeds.
e. Other.

2. Routine inspection audits (pre-operative and ongoing).

a. Steam seals and steam jacketed valves.
b. Piping breaks (clamps).
c. Surge tank seals.
d. Warning lights, sensors, alarms.
e. Inspection of piping at disconnects.
f. Diversionary systems.
g. Bactericide levels or supply.
h. Instruments and recorders.
i. Air filters.
j. Assembly checks.
k. Traps and drains.

3. Operating procedures - references to various manuals.
4. Statement that system cannot be changed without prior FSIS approval.

D. Sanitizing and cleaning procedures (conventional or clean-in-place (CIP)).

1. Methods.
2. Equipment.
3. Solutions, chemicals, sanitizers (list).

E. Pre-operational container checks.

1. Cup-forming (if done).
2. Sealing placement.
3. Seal integrity checks.

F. Presterilization procedures (product equipment and container zones).

1. Letter(s) from process authorities.
2. Written procedures.
3. Critical control points (CCP's).
4. Monitoring (methods and frequencies) of CCP's.

G. Changeover procedures from presterilization to product filling and closing.

1. Concerns regarding pressure drops.
2. Product uniformity.

H. Processing operations.

1. Recommended product sterilization schedules from a process authority (letters).

    a. Continuous flow.
    b. Batch systems.

2. Recommended system operating sterilization schedules from the process authority (container sterilization and system sterility maintenance).

    a. Container zones.
    b. Filler housing.
    c. Sterilant applicators.
    d. Diversion systems.
    e. Other equipment.

3. Critical control point checks.

    a. CCP's.
    b. Monitoring devices.
    c. Frequencies.

I. Coding.

1. Methods.
2. Explanation of code.

J. Closure methods and evaluations.

1. Sealer types (list).
2. Visual inspections.

    a. Incoming materials.
    b. Post-process.
    c. Defect criteria.
    d. Frequencies.

3. Physical tests (incoming, in-process and final).

    a. Methods.
    b. Frequencies.
    c. Defect criteria.
    d. Sampling plans.

4. Bactericide residue monitoring.

    a. Methods.
    b. Frequencies.

5. Lot rejection criteria and corrective actions.

K. Emergency procedures.

1. Package sterilization.
2. Product sterilization.
3. Bactericide residuals.
4. Segregation procedures.

L. Process deviations (handling via MPI Bulletin 79-45 or through a PQC program).

1. Package sterilization.
2. Product sterilization.
3. Loss of sterility.
4. CIP and resterilization procedures.
5. Documentation.
6. Post-process evaluations.
7. Product disposition.

M. Recordkeeping.

1. Copies of all forms.
2. Frequencies of checks.
3. Signature or initialing of records.
4. Review of records.
5. Access by FSIS/USDA.
6. Record retention.

N. Final product testing.

1. Incubation procedures and sampling frequencies (USDA and establishment).
2. Handling of abnormal containers.

    a. MPI Bulletin 79-45.
    b. PQC program.

3. Sterility testing.
4. Condition-of-container examinations.
5. Product disposition.

*U.S. GOVERNMENT PRINTING OFFICE : 1984 0-420-932/FSIS-2197